



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT

850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

dis 17b

Telephone: [718] 965-5300 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL **RETURN RECEIPT REQUESTED**

Bernhard Hampl, Ph.D
Chief Executive Officer
Eon Labs Manufacturing, Inc.
227-15 N. Conduit Avenue
Laurelton, New York 11413

November 4, 1996

Ref: 14-NYK-97

Dear Dr. Hampl:

During an inspection of your drug manufacturing facility located in Laurelton, New York, conducted between the dates of September 19 and October 10, 1996, our investigators documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). Such deviations cause your drug product, Urinary Antiseptic #2 Tablets, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act as follows:

1. Failure to determine conformance with appropriate final specifications. Batches of Urinary Antiseptic # 2 Tablets are not tested for the strength of each active ingredient in finished coated tablets.
2. Failure to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and drug products. The processes for the manufacturing of Urinary Antiseptic #2 Tablets have not been validated.
 - a. Failure to conduct assay testing for each active ingredient in finished coated tablets.
 - b. Uniformity testing consisted of testing for only one of six active ingredients in blends and tablets.
 - c. The full specified range for compression hardness was not evaluated.
 - d. Compression operation speeds were not evaluated.
 - e. Equipment cleaning processes are not validated.

3. Stability data fails to support the expiration date on labels of Urinary Antiseptic #2 Tablets.

- a. Stability batches, 3B063, 3K007, and 4C042 failed to meet potency specifications for phenyl salicylate and/or methylene blue at multiple test intervals.
- b. Stability data fails to include test results for the strength of each active ingredient in the finished coated tablets.

4. Failure to conduct a thorough and documented investigation into repetitive failures of Urinary Antiseptic #2 Tablets, batch 3B063, to meet specifications for phenyl salicylate during stability testing.

5. Failure to follow quality control procedures and written standard operating procedures. Failure to prepare and approve a new formula record, and failure to conduct stability testing for the reprocessing of Urinary Aseptic #2 Tablets, batch 4L013.

6. Production records for Urinary Antiseptic #2 Tablets fail to include complete manufacturing instructions and documentation of each significant step.

- a. During the coating process, the rate of application and the amounts of raw materials added per pan are not specified.
- b. The temperature is not specified for the heating step involving the mixture of methylene blue, [REDACTED] syrup, and [REDACTED] syrup for coating.

The above identification of violations and the observations on the FDA-483 issued at the end of the inspection are not intended to be an all-inclusive list of violations. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering award of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

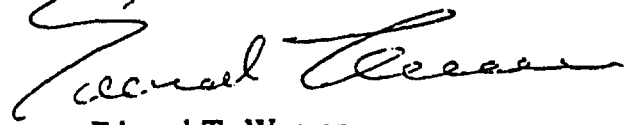
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Eon Labs Manufacturing, Inc.
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Your reply should be sent to Compliance Branch, Food and Drug Administration,
New York District, 850 Third Avenue, Brooklyn, NY 11232, Attention: Laurence D.
Daurio, Compliance Officer.

Sincerely,

A handwritten signature in cursive script, appearing to read "Edward T. Warner".

Edward T. Warner
District Director